36 Meteor Drive
Toronto ON M9W 1A4
[w] 416.674.9500
[f] 416.674.9300
www.sqidiagnostics.com

SECTION 8
510(K) SUMMARY

OCT 29 2009

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is K083080.

807.92 (a)(1):

Name: SQI Diagnostics Systems, Inc.

Address: 36 Meteor Drive
Toronto, Ontario
Canada M9W 1A4

Phone: 416-674-9500 x239

FAX: 416-674-9300

Contact: Ms. Kate Smith

Email: ksmith@sqidiagnostics.com

807.92 (a)(2): Device name- trade name and common name, and classification

Trade name: IgX PLEX™ Rheumatoid Arthritis Qualitative Assay and SQiDworks™ Diagnostics Platform

Common Name: Integrated system for the qualitative detection of IgA and IgM Rheumatoid Factors and IgG antibodies to cyclic citrullinated peptides in serum samples

Classification: Class II

21 CFR 866.5775- Rheumatoid Factor Immunological System

21 CFR 862.2570- Instrumentation for Clinical Multiplex Test

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807.92 (a)(3): Identification of the legally marketed predicate device

The test system is substantially equivalent to other ELISA test kits and microarray systems, specifically the Quanta LITE™ line of reagents (Inova Diagnostics, Inc., San Diego, CA), namely Quanta LITE™ RF IgA ELISA, Quanta LITE™ RF IgM ELISA, and Quanta LITE™ CCP3 IgG ELISA, and the Bioplex™ 2200 Multi-Analyte Detection System (the instrument, Bio-Rad Laboratories, Redmond, WA) respectively.

807.92 (a)(4): Device Description

The device consists of the IgX PLEX™ Rheumatoid Arthritis Qualitative Assay (RL1 kit) and the SQiDworks™ Diagnostics Platform (the Platform); the Platform incorporates the SQiDworks™ Integrated Software (the Software). The Platform is a multiplex immunoassay instrument that fully automates the process of a specific IgX PLEX™ Assay from serum transfer to reporting of all assay markers for each individual patient sample. Once the assay's biochemical reactions have completed, the instrument automatically performs a multi-color fluorescent scan of each well in the microarray, analyzes the data, and generates a report containing qualitative results for all assay markers. The SQiDworks Diagnostics Platform also includes numerous internal quality checks and user safety features with fail-safe and interlock mechanisms.

The instrument integrates an automated pipetting station, a fluorescent scanner, washing and drying stations, and other ancillary hardware components using dedicated instrument control. In addition, the software provides scheduling, self-verification, data acquisition, data management, analysis algorithms and reporting software.

Results for each patient sample from the IgX PLEX™ Rheumatoid Arthritis Qualitative Assay and the SQiDworks™ Diagnostics Platform are obtained simultaneously for each of the three assay markers: RF IgM, RF IgA and CCP IgG using the results from one well containing one aliquot of the patient's serum. Results are reported independently.

The IgX PLEX™ Rheumatoid Arthritis Qualitative Assay (RL1) kit consists of two boxes (with different temperature requirements) of components as described below.

RL1 Kit Components

	Quantity	Container	Volume (each)	Storage
Microarray plate	One (1)	Foil package		2-8°C
Reporter mix	One (1)	Amber bottle	15 mL	≤ -15°C
Calibrators	Eight (8)	2.0 mL tube	400 µL	≤ -15°C
Positive Control #1	One (1)	2.0 mL tube	80 µL	≤ -15°C
Positive Control #2	One (1)	2.0 mL tube	80 µL	≤ -15°C

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Negative control	One (1)	2.0 mL tube	80 µL	≤ -15°C
Sample diluent	One (1)	Translucent bottle	41 mL	≤ -15°C
Wash Buffer Concentrates	Three (3)	Translucent bottle	42 mL	2-8°C
Documentation and batch-specific calibration information	One (1) per shipment	CD-ROM		

IgX PLEX RL1 Microarray Plate

The RL1 microarray plate consists of an array of protein and antibody replicate spots, covalently bound to the surface of coated glass within each well of a standard 96-well assay plate. All wells have the identical configuration of microarray elements, containing:

- Capture spots for Rheumatoid Factor Fc and CCP.
- Internal normalization curve and control spots for internal consistency confirmation.

The outer plate holder is labeled with a barcode indicating the assay type and lot number which is read by the platform.

Reporter Mix

The reporter mix is comprised of diluted fluorescently labeled marker antibodies. There is a marker antibody which is specific to each antibody of interest. In the case of the RL1 assay, the labeled markers are anti-human immunoglobulin antibodies (for example mouse α-hIgM). Each type of marker antibody is labeled with a dye in a different spectral range.

Calibrators/Standards

The external calibrators (standards) are eight dilutions of a sample derived from human sera containing an appropriate representation of each of the analytes to be reported. The assay standards (secondary standards) for RF (IgA and IgM) are traceable to the WHO/First British Standard 64/2 (primary standards) and internally calculated in IU/mL. The CCP IgG results are internally calculated in U/mL and are comparable to other assays on the market. The quantitative results are converted to qualitative results (positive and negative), based on assay-specific cutoff values. No dilutions or reconstitutions are needed.

Controls

The positive and negative control samples are derived from human sera. The platform treats the controls as samples and does not perform any quality assessment based on the

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results. Although expected results for each applicable analyte of each control are provided, each lab is expected to follow their own quality procedures for assessing controls.

Sample Diluent

The sample diluent is a proprietary buffer mix optimized to the requirements of the platform.

Wash Buffer Concentrates

Specific buffer compositions for each wash procedure. The concentrate must be diluted prior to use.

CDROM

One CD is included in each shipment. The contents are a database of lot specific calibration data for each lot in the shipment and the documentation for the user's convenience.

807.92 (a)(5): Intended Use

The IgX PLEX™ Rheumatoid Arthritis Qualitative Assay and SQiDworks™ Diagnostics Platform is an in vitro diagnostic test system for the qualitative detection of the IgA and IgM classes of Rheumatoid Factors and the IgG class of anti-cyclic citrullinated peptide antibodies (CCP-proprietary third generation equivalent formulation) in human serum specimens.

The IgX PLEX™ Rheumatoid Arthritis Qualitative Assay is intended for use in clinical laboratories as an aid in the diagnosis of Rheumatoid Arthritis in conjunction with other laboratory and clinical findings, and requires the SQiDworks™ Diagnostics Platform.

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807.92 (a)(6): Technological Similarities and Differences to the Predicate

IgX PLEX™ Rheumatoid Arthritis Qualitative Assay		Predicate(s)
Aspect/Feature/Characteristic	**IgX PLEX RF IgA**	**QUANTA Lite™ RF IgA K983084**
Intended Use	As aid in diagnosis of rheumatoid arthritis	Same
Sample Matrix	Serum	Same
Methodology	Microarray-based fluorescent detection	ELISA
Calibration	On each plate	Same
Concentration Determination	Qualitative	Semi-Quantitative
Expected Value	Cut-off is 12.0 IU/mL	Cut-off is 6 U/mL
Assay Substrate	96-well microarray plates	96-well microtiter plates
Multiplexed Assay	Yes	No
Aspect/Feature/Characteristic	**IgX PLEX RF IgM**	**QUANTA Lite RF IgM K971614**
Intended Use	As aid in diagnosis of rheumatoid arthritis	Same
Sample Matrix	Serum	Same
Methodology	Microarray-based fluorescent detection	ELISA
Calibration	On each plate	Same
Concentration Determination	Qualitative	Semi-Quantitative
Expected Value	Cut-off is 18.2 IU/mL	Cut-off is 6 U/mL
Assay Substrate	96-well microarray plates	96-well microtiter plates
Multiplexed Assay	Yes	No
Aspect/Feature/Characteristic	**IgX PLEX Anti-CCP IgG**	**QUANTA Lite CCP3 IgG K052264**
Intended Use	As aid in diagnosis of rheumatoid arthritis	Same
Sample Matrix	Serum	Same
Methodology	Microarray-based fluorescent detection	ELISA
Calibration	On each plate	Same
Concentration Determination	Qualitative	Semi-Quantitative
Expected Value	Cut-off is 11.7 U/mL	Cut-off is 20 U/mL
Assay Substrate	96-well microarray plates	96-well microtiter plates
Multiplexed Assay	Yes	No

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Aspect/Feature/Characteristic	SQiDworks Microarray Diagnostic Platform	BioPlex™ 2200 Multi-Analyte Detection System K041658
Multi-analyte	Yes	Same
Multiplexing Method	Based on multiplex microarray based technology	Based on multiplex, bead-based technology
Detection Type	Fluorescence	Same
Target of Detection	Microarray Spot	Bead
Detector	Multichannel fluorescence CCD camera scanner	Laser monochromatic bead flow cytometry-like reader
Sample Handling and Processing	Automated	Same
Reagent Storage	No reagent storage	On-board, refrigerated reagent storage
Internal Controls	Blank, serum verification	Same
Internal Controls	Reaction condition verifications	No
Assay Substrate	96-well microarray plates	Individual cuvettes
Calibration	External calibrators	Same
Laboratory Environment	Traditional laboratory environment	Same

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807.92 (b)(1) and (b)(2): Brief Description of Nonclinical and Clinical Data

A series of nonclinical (in-house) studies were conducted in support of the performance characteristics for the IgX PLEX™ Rheumatoid Arthritis Qualitative Assay and SQiDworks™ Diagnostics Platform. Those characteristics are defined as follows:

- Reproducibility ranges were 95.0%-100% for RF IgA, 96.3%-100% for RF IgM and 83.3%-100% for CCP IgG.
- Clinical sensitivity ranged from 77.7% (CCP IgG) to 93.3% (RF IgM) and clinical specificity ranged from 92.7% (RF IgA) to 96.0% (CCP IgG). This performance is consistent with literature references. In this study, clinical diagnosis (RA or non-RA, including normals) was used as the reference result.
- Overall agreement between the analytes in the IgX PLEX™ Rheumatoid Arthritis Qualitative Assay and established predicate test systems ranged from 85% (RF IgA) to 95% (CCP IgG).
- None of the analytes in the assay were affected by high levels of the following biological substances: bilirubin, hemoglobin, triglycerides and human IgG.

807.92 (b)(3): Conclusions from Nonclinical and Clinical Testing

Nonclinical and clinical testing was performed for the IgX PLEX™ Rheumatoid Arthritis Qualitative Assay and SQiDworks™ Diagnostics Platform. The test system was shown to be safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

SQI Diagnostics Systems
c/o Ms. Kate Smith
36 Meteor Drive
Toronto, ON
Canada M9W 1A4

OCT 29 2009

Re: k083080
Trade/Device Name: IgX PLEX™ Rheumatoid Arthritis Qualitative Assay and SQiDworks™ Diagnostics Platform
Regulation Number: 21 CFR §866.5775
Regulation Name: Rheumatoid Factor Immunological System
Regulatory Class: Class II
Product Code: DHR, NHX, NSU
Dated: October 9, 2009
Received: October 13, 2009

Dear Ms. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or

any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(K) Number (if known): K083080

Device Name:

IgX PLEX™ Rheumatoid Arthritis Qualitative Assay and SQiDworks™ Diagnostics Platform

Indications for Use:

The IgX PLEX™ Rheumatoid Arthritis Qualitative Assay and SQiDworks™ Diagnostics Platform is an in vitro diagnostic test system for the qualitative detection of the IgA and IgM classes of Rheumatoid Factors, and the IgG class of anti-cyclic citrullinated peptide antibodies (CCP-proprietary third generation equivalent formulation) in human serum specimens.

The IgX PLEX™ Rheumatoid Arthritis Qualitative Assay is intended for use in clinical laboratories as an aid in the diagnosis of Rheumatoid Arthritis in conjunction with other laboratory and clinical findings, and requires the SQiDworks™ Diagnostics Platform.

Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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